

## REMARKS

Dr. Wardlaw and the undersigned attorney thank Examiner Hammond and SPE Warden for participating in a telephone conference in which aspects of the present application were discussed. No agreement was reached on the outstanding rejections, but the conversation was helpful.

4. Claims 34-36 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the rejection indicates that the specification “implies” that the separators are part of the first or second planar member. Applicant respectfully disagrees with the characterization of the present specification and the rejection based thereon.

Paragraph [0016]<sup>1</sup> of the present application recites that the “separators 16 are disposed between the members 12, 14, and separate the planar members 12, 14 to form a chamber 18 having a height 20”. There is no requirement or suggestion that the separators are “part” of either the first or second planar member. On the contrary, the separators are described in the present specification as independent of the planar members (see e.g., [0017, 0021]), including instances where the separators are described as comprising a different material; e.g., separators 16 formed from a material that has greater flexibility than the first planar member 12 and the second planar member 14. (see [0018]).

Paragraph [0025] of the present application provides that the separators 16 “are randomly distributed on at least one of the planar members 12, 14 and *can* be attached as part of the reagent film containing the staining material.” (emphasis added) This statement does not require the separators be attached to either planar member, but rather gives an embodiment wherein the separators *can* be attached to one of the members, and then describes how that may be accomplished. The applicant agrees that as presently recited in claim 34, the separators are independent of the planar members and are therefore not formed as a part of the first or second planar members.

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<sup>1</sup> For clarity sake, all references to paragraph numbers are based on those paragraph numbers used in the application as filed.

7. Claims 1-3 and 11 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,632,652 (referred to hereinafter as “Austin”). Specifically, the rejection provides that Austin teaches an apparatus (80) having a first planar member (26), a second planar member (88), wherein at least one of the first planar member and second planar members is transparent, at least three separators (62) disposed between the planar members, each separator individually having a height and the separators collectively having a mean height, and wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable. Applicants respectfully disagree with the characterization of Austin and the rejection based thereon.

The classic test for anticipation, under 35 U.S.C. §102, requires that every limitation in a claim must be present in a single source reference for that reference to “anticipate” the claimed invention.

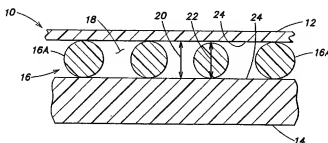
Amended claim 1 of the present application recites as follows:

1. An apparatus for analyzing biologic fluid, comprising:
  - a first planar member;
  - a second planar member, wherein at least one of the first planar member and second planar member is transparent; and
  - at least three separators disposed between the planar members, each separator individually having a height and the separators collectively having a mean height, separating the planar members to form a chamber having a height extending between the planar members;
  - wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable when the first planar member and second planar member are drawn toward one another by capillary force from a biologic fluid quiescently residing within the chamber to cause the mean chamber height to be substantially equal to the mean height of the separators.

Austin does not disclose the elements recited in claim 1, and therefore cannot “anticipate” the invention recited in claim 1.

#### Austin Does Not Describe an Apparatus Having Two Planar Members

Claim 1 recites an apparatus having a first *planar* member and a second *planar* member. (emphasis added) The American Heritage Dictionary (1981) defines the term “planar” as “of, pertaining to, or situated in a plane”, “flat”, “level surface”. The present specification provides that the planar members may be comprised of a film or a tape. FIGS. 3-6 of the present application clearly show that the planar members have flat interior surfaces contiguous with the chamber 18, and those surfaces are substantially parallel with each other.



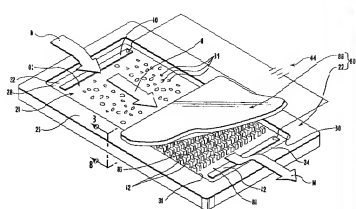
Applicant respectfully submits that the term “planar” cannot be ignored. *See, e.g., In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970) (“All words in a claim must be considered in judging the patentability of that claim against the prior art”) *See also* M.P.E.P. 2143.03.

Austin, in contrast, discloses a sorting apparatus 80 that includes an elongated substrate 82 that includes a cavity (referred to as a “receptacle 24”) disposed within a side surface 26 of the substrate 82. The receptacle 24 is defined by a floor 28, side walls 30, 31, and first and second ends 32, 34. Bunkers 62 extend outwardly from the floor 28. Austin discloses further that a cover 88 is in contact with the side surface 26 of the substrate 82. (Col. 9, lines 37-53; Col. 3, lines 5-55; *see* FIGS. 1-4 and 7) Consequently, Austin does not disclose two planar members with separators disposed between them, and cannot therefore anticipate the apparatus of claim 1.

Austin Does Not Describe a Structure having a First Planar Member, a Second Planar Member, and Separators, At Least One of Which is Sufficiently Deformable Under Capillary Force to Cause the Mean Chamber Height to be Substantially Equal to the Mean Height of the Separators

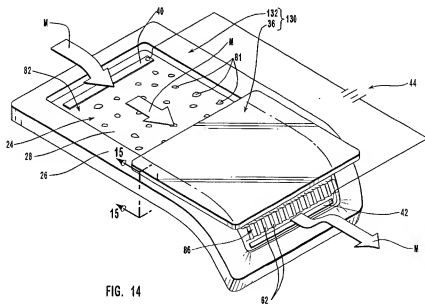
Applicant first notes that the Office Action of March 23, 2010 provides that “Austin does not specifically teach an apparatus wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable and wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable”. (see page 7) Applicant also notes that the Office Action of March 23, 2010 further provides that “Austin does not specifically teach an apparatus wherein the separators are deformable relative to the first planar member and the second planar member.” (Office Action pgs. 5 and 6) For at least these reasons, applicant respectfully submits that Austin does not anticipate the apparatus of claim 1.

Austin describes a microstructure sorting device as having a substrate 82/22 with a shallow receptacle 24 located within a side 26 of the substrate. (col. 2, lines 59-67) As indicated above, the receptacle 24 includes a floor 28 bounded by walls 30, 31, and ends 32, 34. The microstructure sorting device according to Austin is a device 80 wherein “one of the cover or the substrate is comprised of an elastomer.” (Col. 7, lines 46-47) In one embodiment, the device 80 includes an elastomeric cover 88 that engages the top 66 of each bunker 62 in an array 86. According to Austin, the cover 88 is in contact with the top of the bunkers 62 to prevent migration of microstructures between the bunker tops 66 and the cover 88. (Col. 3, lines 48-50) The purpose of the elastomeric cover 88, according to Austin therefore, is to permit the cover 88 to flex and be nondestructively removable from the substrate 22, and to prevent migration of microstructures between the bunker tops 66 and the cover 88. (Col. 10, lines 4-15)



There is no disclosure whatsoever within Austin regarding the flexibility of the cover 88, other than its ability to be removed from the substrate 82/22. Hence, there is no disclosure that the cover 88 can be deformed by capillary action, and specifically no disclosure that the cover 88 can be deformed by capillary force from a biologic fluid quiescently residing within the chamber to cause the mean chamber height to be substantially equal to the mean height of the separators.

In a separate embodiment, Austin discloses that the coverslip 36 is rigid and the substrate 132 containing the cavity in which the bunkers 62 are disposed is flexible. (Col. 11, lines 23-32).



Here again, there is no disclosure whatsoever within Austin regarding the flexibility of the substrate 132, other than its ability to be removed from the rigid coverslip 36. Hence, there is no disclosure that the substrate 132 can be deformed by capillary action, and specifically no disclosure that the substrate 132 is sufficiently deformable by capillary force from a biologic fluid quiescently residing within the chamber to cause the mean chamber height to be substantially equal to the mean height of the separators.

The aspect recited within claim 1, that at least one of the first planar member, second planar member, or separators is sufficiently deformable when the first planar member and second planar member are drawn toward one another *by capillary force* from a biologic fluid quiescently residing within the chamber to cause the mean chamber height to be substantially equal to the mean height of the separators, is significant and is one of the factors that distinguishes the present apparatus. Applicant respectfully directs the Examiner to paragraphs [0003] and [0005-0007] of the present application wherein the problems of the prior art are explained. As indicated, a couple of the significant problems associated with “precisely manufactured” prior art chambers (e.g., similar to that disclosed within Austin) is that they are very expensive and difficult to manufacture. With respect to the counting chambers formed between rigid upper and lower panels separated by rigid particles, these chambers are subject to the dimensional inaccuracies of the particles and do not, therefore, consistently provide the requisite dimensional accuracy necessary for the sample analysis. Paragraphs [0011-0013] of the present application clearly describe how the present invention overcomes these problems; e.g., the present invention chamber can be formed inexpensively from commercially available film and beads, and provides the desired chamber geometry accuracy without machining, dies, etc.

The rejection provides that “elastomeric materials are polymeric materials with large amounts of reversible deformability when the first planar member and the second planar member are drawn toward one another by capillary force”. The rejection then indicates that Austin discloses that the height and the width of the bunkers 62 are between 1-50 $\mu$ m and 0.01-20 $\mu$ m, and that “this range encompasses the disclosed range of 4 $\mu$ m in the instant application”. Consequently, according to the rejection, “the apparatus of Austin is capable of creating capillary force when a biological fluid is present between

the first planar member and the second planar member”. Applicant respectfully disagrees.

First, there is absolutely no basis within the reference for the statement “elastomeric materials are polymeric materials with large amounts of reversible deformability when the first planar member and the second planar member are drawn toward one another by capillary force. Second, the present application is not limited to a “disclosed range of 4μm”; e.g., “The chamber height 20 is not limited to the disclosed four microns but can be smaller or larger”. (see [0035]) Third, whether or not capillary forces may exist within the receptacle 24 disclosed within Austin is a wholly different issue than whether the substrate 82/22 or the coverslip 88 is of a type that is sufficiently deformable when subjected to capillary force from a biologic fluid quiescently residing within the chamber to cause the mean chamber height to be substantially equal to the mean height of the separators. As indicated above, there is nothing within Austin that teaches a first planar member, a second planar member, or separators that are sufficiently deformable when subjected to capillary force from a biologic fluid quiescently residing within the chamber to cause the mean chamber height to be substantially equal to the mean height of the separators.

For at least the reasons provided above, applicant respectfully submits that Austin does not anticipate or suggest the apparatus recited within independent claim 1, and therefore dependent claims 2, 3, and 11.

10. Claims 4-6 and 33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Austin. The rejection provides that separators “which are made of an elastomer, would be more deformable than a very rigid material such as silicon. Furthermore, the separators being very small projections made of the same material as the first planar member 26 would have greater deformability than the large base.” Applicants respectfully disagree with this characterization of Austin and the rejection based thereon.

Applicants respectfully direct the Examiner to the remarks above regarding claim 1. For at least those reasons, applicant respectfully submits the rejection is without merit.

In addition, applicant respectfully submits that the relative deformability of the materials of the substrate 82, the bunkers 62, and the cover 88 do not arrive at the claimed invention. As indicated above, Austin teaches a first embodiment wherein a

rigid substrate 82 (which is integral with bunkers 62) is used with an elastomeric cover 88, and a second embodiment wherein an elastomeric substrate 82 (which is integral with bunkers 62) is used with a rigid cover 88. Neither of these embodiments disclose or suggest an apparatus: 1) wherein a first planar member, a second planar member, or separators that are sufficiently deformable when subjected to capillary force from a biologic fluid quiescently residing within the chamber to cause the mean chamber height to be substantially equal to the mean height of the separators (claim 1); or 2) wherein a first planar member and a second planar member are sufficiently deformable when subjected to capillary force from a biologic fluid quiescently residing within the chamber to cause the mean chamber height to be substantially unaffected by the presence of debris in the chamber, which debris has a height greater than the mean separator height (claim 33). As indicated above, the relative deformability of the elements *when subjected to a capillary force* is significant within the claimed invention and is not disclosed or suggested within Austin.

Present claim 4 recites that the separators are deformable relative to the first and second planar members. Since Austin only discloses embodiments wherein the bunkers are integral with the substrate 82, Austin cannot disclose the apparatus of claim 4 because the separators cannot be deformable relative to the first and second planar members. The suggestion that because “separators being very small projections made of the same material as the first planar member (26) would have greater deformability as the large base” is without merit for at least three reasons. First, there is no basis for the suggestion within the references, and it appears therefore to be the product of impermissible hindsight. *See, e.g.*, MPEP § 2142 (“The tendency to resort to ‘hindsight’ based upon applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.”). Second, even if the bunkers 62 did deform as is suggested, there is no disclosure or suggestion that they would do so as a result of capillary force from a biologic fluid quiescently residing within the chamber, in an amount that would cause the mean chamber height to be substantially equal to the mean height of the separators. Third, the deformation suggested within the rejection would likely make the sorting apparatus inoperable for its intended use.



Austin describes a microstructure sorting device having a receptacle 24 disposed in the surface of a substrate, with an array 38 of obstacles 39 or bunkers 62 extending outwardly from the floor 28 of the receptacle 24. The obstacles / bunkers 62 within the array are disposed in an “ordered and uniform pattern”. (Col. 4, lines 24-27) The pores 54 formed between bunkers are “constant and reproducible”. (Col. 4, lines 28-49) The fact that the pores 54 are “constant and reproducible” teaches away from deformable bunkers 62 which would necessarily deflect into the pores 54 and thereby make distance between adjacent bunkers 62 non-constant. As a result, the ability of the sorting device to properly operate would be compromised.

In addition, even if the obstacles 39 or bunkers 62 were deformable as the rejection suggests, the obstacles/bunkers would not dictate the height of the receptacle 24. As can be seen in FIG. 14, the rigid coverslip 36 clearly extends across the entire receptacle 24. As a result, the height of the interior chamber is a function of the tolerances of the flexible substrate 132, the receptacle 24, and the rigid coverslip 36. The allegedly deformable obstacles / bunkers would not affect the height of the receptacle 24.

Regarding the suggestion within the rejection (p. 6) that “the base could be made sufficiently thin so that it is more deformable relative to the separators”, applicant respectfully disagrees and submits that the aforesaid statement appears to be the product of impermissible hindsight. *See, e.g.*, MPEP § 2142 (“The tendency to resort to ‘hindsight’ based upon applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.”). As indicated above, the sorting device taught by Austin includes an array 38 of bunkers 62 that are disposed in an “ordered and uniform pattern” to create pores 54 having “constant and reproducible” sizes. (Col. 4, lines 24-49) The pore 54 size is critical to perform the sorting function of the device. The fact that the pores 54 are “constant and reproducible” teaches away from a receptacle having a deformable base because it would introduce variability into the pore sizes. As a result, the ability of the sorting device to properly operate would be compromised.

13. Claims 8 and 9 are rejected under 35 U.S.C. §103(a) as being unpatentable over Austin in view of U.S. Patent No. 4,883,642 (referred to hereinafter as “Bisconte”).

Claims 8 and 9 depend from claim 1. Applicant directs the Examiner to the comments above and respectfully submit for at least those reasons, the subject matter of claims 8 and 9 is not obvious in view of Austin and Bisconte.

14. Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Austin in view of U.S. Patent No. 6,551,554 (referred to hereinafter as “Vermeiden”). Specifically, the rejection provides that Austin teaches the use of a dye to allow for visualization of blood cells, and Vermeiden teaches the use of plastic beads. Applicant respectfully disagrees with the characterizations of the cited references and the rejection based thereon.

Claim 10 depends from claim 1. Applicants direct the Examiner to the comments above and respectfully submit for at least those reasons the subject matter of claim 10 is not obvious in view of Austin and Vermeiden.

In addition, Austin discloses the use of dyes to stain *cells* within a sample. Austin does not, however, teach or suggest the use of uniformly dyed slightly compressible plastic beads. Vermeiden discloses the use of particles 8. There is no disclosure within Vermeiden, however, regarding particles that are uniformly dyed or that are slightly compressible. On the contrary, Vermeiden discloses particles that may be made of plastic, or aluminum oxide, or glass. (Col. 4, lines 16-22) There is no disclosure of any of these materials as being slightly compressible, and aluminum oxide, glass, and many plastics are typically considered to be incompressible.

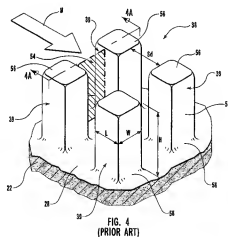
Vermeiden also discloses that “the material particles 8 having the largest dimensions will determine the depth of the counting compartment 1” (Col. 3, lines 33-35), and “the material particles 8 can of course contain smaller particles 8, but they do not determine the distance between the bottom plate 2 and the top plate 3.” (Col. 4, lines 5-9) Clearly, from these passages it can be seen that the larger sized particles 8 do not compress within the chamber (even if they are plastic). In fact, the described apparatus suffers from the problem to which the present invention provides a solution. Hence, Vermeiden actually teaches away from the proposed combination.

15. Claim 12 is rejected under 35 U.S.C. §103(a) as being unpatentable over Austin in view of U.S. Patent No. 7,179,423 (referred to hereinafter as “Böhm”).

Claim 12 depends from claim 1. Applicants direct the Examiner to the comments above and respectfully submit for at least those reasons the subject matter of claim 12 is not obvious in view of Austin and Böhm.

16. Claims 34-36 are rejected under 35 U.S.C. §103(a) as being unpatentable over Austin in view of U.S. Patent No. 4,950,455 (referred to hereinafter as “Smith”). The rejection provides that “Austin does not teach separators that are independent of the first planar member and the second planar member, and are randomly distributed”, but then indicates that it would have been obvious to one of ordinary skill in the art to include separators that are independent from the planar members and that are randomly distributed in the Austin apparatus in view of Smith for the benefit of creating a known chamber height. Applicant respectfully disagrees with the characterization of the references and the rejection based thereon.

The sorting apparatus taught by Austin relies upon an array 38 of bunkers 62 that are disposed in an “ordered and uniform pattern” to create pores 54 having “constant and reproducible” sizes. (Col. 4, lines 24-49) The pore 54 size is critical to perform the sorting function of the device.



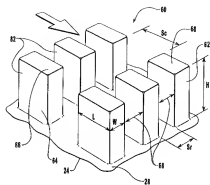


FIG. 5  
(PRIOR ART)

Austin also discloses that the cover 88 must be sealed to the top of the bunkers 62 to prevent migration of cells between the tops 66 and the cover 88. These attributes of Austin directly teach away from the combination proposed with Smith. If beads like those disclosed in Smith were randomly distributed within a sorting device like that taught by Austin, the beads would compromise the ability of the sorting device to function as a sorting device. The sorting device relies upon the predetermined spacing within the array to function properly.

In addition, the cited reason for combining the references to create “a known chamber height” is the product of impermissible hindsight. The configuration of Austin includes structure (e.g., bunkers 62) to establish receptacle height. Consequently, the addition of beads is without purpose.

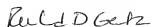
For at least these reasons, applicant respectfully request the rejection be withdrawn.

New claims 37-39 have been added directed toward those aspects which the applicant considers to be the invention, and which subject matter is well within the scope of the invention claimed to date and disclosed within the present application.

As the applicant has traversed all the rejections raised by the Examiner, it is respectfully requested that the Examiner withdraw the stated rejections, allow claims 1-12 and 33-39, and pass the present application on to issuance. Please charge the fee for a

one month extension to deposit account no. 50-3381. In the event an additional fee is due, please also charge our Deposit Order Account No. 50-3381.

Respectfully submitted,



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